

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Racz et al.

Serial No.: 10/694,235

Filed: October 27, 2003

For: SAFETY SPINAL NEEDLE
(As Amended)

Confirmation No.: 3743

Examiner: V. Campbell

Group Art Unit: 3763

Attorney Docket No.: 2102-4389US

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APRIL 6, 2012

REPLY BRIEF

Mail Stop Appeal Brief – Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply Brief is submitted in response to particular statements and assertions presented in the Examiner's Answer of February 7, 2012. Pursuant to 37 C.F.R. § 41.41, the Appellants do not believe this Reply Brief includes any new amendment, or any new or non-admitted affidavit or other evidence. Appellants courteously submit that dictionary definitions presented herein are not "evidence" within the meaning of 37 C.F.R. § 41.41, for at least the reason that treating dictionary definitions in this manner is consistent with judicial precedent, which provides that dictionaries may be consulted by tribunals "at any time." *See, e.g., Nix v.*

Hedden, 149 U.S. 304, 307 (1893); *see also* 76 FR 72273, first column, November 22, 2011 (providing “clarity” in new Rules of B.P.A.I. Practice that dictionary definitions are not evidence within the meaning of 37 C.F.R. § 41.41).

The observations and remarks presented herein refer to and supplement the contents of the Appeal Brief of November 21, 2011.

I. OVERVIEW

At issue in the present case are three very similar rejections under 35 U.S.C. § 103(a) over U.S. Patent 5,871,470 (hereinafter “McWha”) and U.S. Patent 5,250,035 (hereinafter “Smith”), either as a pair, or in view of an additional reference.

Appellant respectfully submits that it should be clear from the record of this case, including Appellant’s Brief on Appeal and the Examiner’s Answer, that the combination of McWha and Smith is not sufficient to render any of the present claims obvious. Specifically, the claims are drawn to a completely new and advantageous arrangement of a flexible catheter and a rigid support needle. While McWha and Smith also relate to epidural devices, neither of them independently or in combination even remotely suggests the particular arrangement of the claimed assemblies. In order to deform the design described in McWha and Smith into one resembling the claimed devices, the Examiner must either pretend that the needle of McWha is a flexible catheter, or else that the flexible catheter of Smith is a needle. The Examiner has presented this necessary distortion of the cited references as a simple change in the material from which elements of the assemblies are manufactured. However, it in fact represents a complete reimagining of the prior art needle and catheter assemblies.

The foregoing is further illustrated by reference to specific comments of the Examiner, as set forth below.

II. RESPONSES TO SPECIFIC ASPECTS OF THE EXAMINER'S ANSWER

A) In the Examiner's Answer, the Examiner asserts with regard to the combination of McWha and Smith,

Although applicant has disclosed many reasons why McWha and Smith et al differ, applicant has failed to recognize the fact that the systems of the McWha and the Smith et al references are both drawn to epidural needles for insertion in the spinal column of a patient. As such, one having ordinary skill in the art, looking to make an improved spinal catheter, would look to both the McWha and Smith et al references and, appreciating the benefits of various aspects thereof, combine their teachings to arrive at the claimed invention.

Examiner's Answer, at page 14.

Appellant acknowledges that both McWha and Smith relate to epidural devices.¹ However, both of these references describe devices for inserting and positioning a flexible cannula into a patient's body, where the cannula is inserted through an opening created by a rigid cutting tool (*i.e.*, needle). In contrast, the presently claimed device employs a flexible cannula with a needle that is removably disposed within the cannula. This is a difference that was not represented in the art prior to the present invention, and would not have been contemplated by one of ordinary skill in the art at the time the invention was made.

At most, the Examiner has proposed that the steel (or at least sufficiently rigid) needle of McWha would have been fabricated from a flexible plastic, because a plastic cannula is described in Smith (which cannula needs to be inserted through a pre-existing opening made by a rigid needle). The Examiner's proposal does not appreciate the fundamental difference in operation between the claimed assemblies and the prior art; the present invention is much more than a simple choice of alternative manufacturing materials.

¹ However, the Examiner is incorrect that Smith describes "epidural needles for insertion in the spinal column of a patient." See Examiner's Answer, at page 14. The cannula of Smith is inserted into a *previously formed* puncture in a patient's back. Smith, at col. 3, lines 22-25.

B) In the Examiner's Answer, the Examiner asserts with regard to the explanation of the meaning of McWha and Smith in Appellant's Brief on Appeal,

Applicant appears to rely on the fact that McWha did not provide alternative materials for the composition of the catheter in their specification. However, the absence of alternatives in the prior art does not preclude substitution should useful properties of another suitable material be recognized.

Examiner's Answer, at pages 14-15.

By this statement, it is evident that the Examiner has misunderstood the substance of Appellant's explanation. Appellant apologizes if the Brief on Appeal was not sufficiently clear.

Appellant does not rely on the fact that McWha recites stainless steel as a preferable material from which its needle cannulas are to be manufactured, or the fact that it is the only such material described in McWha. The relevant question to obviousness under 35 U.S.C. § 103 is not whether substitution is precluded, but whether the substitution would be operable, and whether the substitution would have been made by one of ordinary skill in the art at the time of the invention. In the Brief on Appeal, Appellant intended to explain that the description of needles in McWha is one piece of evidence that tends to show that Appellant's position is more likely than not; that one of ordinary skill would not have thought to fabricate an epidural needle as described in McWha from a flexible plastic, and that if such a fabrication had been for some reason attempted, it would not have been operable for its intended purpose.

On this point, the Examiner and Appellant appear to have a fundamental disagreement about whether a plastic flexible needle catheter can both have "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," as claimed, and yet be suitable for cleanly piercing/cutting the skin and tissue of a patient when used as a needle, as described in McWha. In regard to this disagreement, Appellant notes that the Examiner has not provided even a single piece of evidence beyond mere speculation that such a flexible plastic needle would be functional in the system of McWha, or that one of no more than ordinary skill in the art would have been inclined to make and use epidural needles for puncture and insertion as described by McWha and Smith out of plastic having the claimed degree of flexibility.

On the other hand, Appellants have identified the following evidence that supports the contrary position:

1. McWha does not describe that its epidural needle can be manufactured from any plastic, let alone a plastic with the claimed flexibility (McWha, at col. 7, line 67, to col. 8, line 2);

2. McWha does expressly describe that every other component except for the needle of its assembly can be manufactured from plastics (McWha, at col. 7, lines 63-64; and col. 8, lines 2-4); and

3. Smith describes a plastic cannula, but Smith expressly explains that its plastic cannula requires a pre-existing opening made by a rigid needle for insertion (*i.e.*, the plastic cannula of Smith cannot suitably cut and penetrate the skin and tissue of a patient as required by the epidural needle of McWha). Smith, at col. 3, lines 22-25

The foregoing facts, together with the complete absence in the record of any prior art epidural needle made of flexible plastic, strongly indicate that an epidural needle fabricated from flexible plastic would not function as required by McWha. These facts perhaps even more strongly indicate that an ordinarily skilled artisan would not have been motivated to manufacture a flexible plastic epidural needle to replace the steel needles used in the art.

C) In the Examiner's Answer, the Examiner states that because Appellant has allegedly "not quantified the degree of flexibility and/or patient movement intended to be accommodated by the flexible needle catheter," the Examiner has "considered any degree of 'give' within the flexible needle catheter to be sufficient to fulfill the claim limitation." Examiner's Answer, at page 15.

Appellant courteously submits that this treatment of the claim element, "possess[ing] sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," is obvious error. The fact that the claim does not recite a quantity of some unit of measuring tensile strength of an object does not mean that "any degree" of flexibility will satisfy the foregoing element. This element means exactly what it says; if a plastic flexible needle catheter does not possess "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," it

does not fall within the scope of the claim.

While there may be a variety of possible plastic flexible needle catheters that will satisfy this claim element, this element clearly distinguishes the claimed catheters from the outer needle in prior art catheter assemblies (as opposed to the inner catheter of such assemblies). It is error for the Examiner to disregard this element, or to consider it satisfied by any catheter.

D) In the Examiner's Answer, the Examiner asserts with regard to the claim element, "leading edge,"

The examiner has given the term "leading edge" its broadest reasonable interpretation to include the entire beveled edge of the flexible needle catheter. As such, the opening [in the combination of McWha and Smith] is contiguous with the leading edge. Applicant appears to be intending the leading edge to refer only to the insertion tip, but the examiner notes this is an unduly narrow interpretation of the claim language.

Examiner's Answer, at page 16.

The Examiner's interpretation of "leading edge" is not reasonable. In fact, the Examiner appears to be interpreting "leading edge" to refer to a surface. This is not the art-recognized meaning of this term. At least with regard to medical devices, an "edge" is defined as "[a] line at which a surface terminates." Stedman's Medical Dictionary, 27th Edition, Lippincott Williams & Wilkins, 2000, Baltimore, MD. Even in general use, an "edge" is, for example, "the line where an object or area begins or ends." Merriam-Webster's Collegiate Dictionary, 11th Edition, Merriam-Webster, Inc., 2003, Springfield, MA.

Thus, McWha does not describe an opening in a support needle that is "positioned contiguous to the leading edge of [a] flexible needle catheter." For example, FIGs. 3 and 6 of McWha show that the spinal needle passes through a surface (or area) of the steel epidural needle as it enters the patient. The opening in the spinal needle never is contiguous with the line where this surface/area terminates (or begins or ends). Although the edge of the epidural needle of McWha is not specifically identified in the figures therein, it is marked in FIG. 3 of McWha as one boundary of distance "x."

E) In the Examiner's Answer, the Examiner asserts with regard to the steel spinal needle of McWha,

[T]he flexible needle cannula of McWha as defined by the examiner, allows for the passage of the support needle therein, and therefore fulfills any and all limitations of the term "cannula" as understood in the art. It is noted that the features upon which applicant relies (i.e., that fluid must be delivered through the tube in order for it to function as a cannula) are not recited in the rejected claim(s).

Examiner's Answer, at page 16.

First, Appellant notes that the Examiner appears to be referring to the "catheter" of, for example, claim 16, as the foregoing assertion appears in the portion of the Examiner's Answer that is directed to claims 16-18, 20, 21, and 23. Examiner's Answer, at page 16.

Second, the Examiner's interpretation of the recited claim element of a "catheter" is not reasonable. The Examiner appears to be asserting that the claimed "catheter," which corresponds in the Examiner's combination of McWha and Smith to the steel epidural needle cannula of McWha, does not need to be able to deliver fluid through its bore, because this is not expressly recited in the claim. However, the claim clearly states that this element is a "catheter." A catheter is, without more explanation, "[a] tubular instrument *to allow passage of fluid* from or into a body cavity or blood vessel." Stedman's Medical Dictionary, 27th Edition, Lippincott Williams & Wilkins, 2000, Baltimore, MD (emphasis added). The Specification of the present application is entirely consistent with this common usage. The element in the Examiner's proposed combination of McWha and Smith that corresponds to the claimed "catheter" is absolutely not the tubular instrument in the resulting assembly that allows passage of fluid into the body cavity of the patient.

III. CONCLUSION

Appellant respectfully requests that the Board take the foregoing observations and remarks into consideration when reviewing the Brief on Appeal and Examiner's Answer in the context of the record assembled in this case during prosecution. Appellant courteously submits that a review of all these materials will unmistakably demonstrate that one of ordinary skill in the art at the time of the invention would not have combined McWha and Smith in the manner suggested by the Examiner to arrive at any of the presently claimed subject matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Alexander T. Stein', with a large, stylized flourish at the end.

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